

## REMARKS

Claims 1-6, 8-22 and 24-29 are pending in the subject application.

Applicants note that in the Amendment filed on August 11, 2009, new claims 25-29 were added. However, based on the November 25, 2009 Office action, none of these new claims are reflected in the "Disposition of Claims" section or in the Detailed Action. For example, none of these new claims are addressed in the Claim Rejections or in the Allowable Subject Matter. Applicants further note that in the Detailed Action, it appears that none of Applicants' amendments to the claims (e.g. independent claims 1 and 24) were addressed. Thus, Applicants re-submit similar arguments herein and request consideration by the Office.

Applicants request reconsideration based on the amendments and the following remarks.

### 1. 35 U.S.C. §102 Rejections

Claim 1 is rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,725,493 to Avery et al. (hereinafter "Avery"). Applicants respectfully traverse.

In the November 25, 2009 Office Action, Applicants wish to note that the amendments to claim 1 are not addressed. In particular, in Applicants' August 11, 2009 Amendment, claim 1 was amended so as to recite a securing mechanism near the distal end of the cannula configured to secure a distal portion of the cannula to the retina.

Applicants submit that Avery at least does not teach or suggest a securing mechanism near the distal end of the cannula, the securing mechanism configured to secure a distal portion of the cannula to the retina. Rather, according to Avery, a preformed delivery tube 140 extends from a housing 80. The preformed tube 140 has sufficient rigidity to maintain a longitudinal curvature along the outer surface of the

eyeball (as shown in Figs. 5-6) (see, e.g. col. 6, lines 28-33), and a semi-rigid tubular elbow 160 extends from the end of tube 140 and at an angle (e.g. 80-90°) downwards to terminate in the vitreous (see, e.g. col. 6, lines 34-40; Figs. 2-6). As set out, “the rigidity of the elbow allows the position of the intravitreal extension to be controlled as it is inserted into the cavity” (col. 7, lines 5-9) and the “rigidity of the elbow and its attachment to the sclera (FIGS. 1 and 2) maintain the intravitreal extension of the implant tube in the position in which it is initially placed so that it does not move around in the cavity as the implant is worn and used by the patient.” (Col. 7, lines 18-22) as shown below:

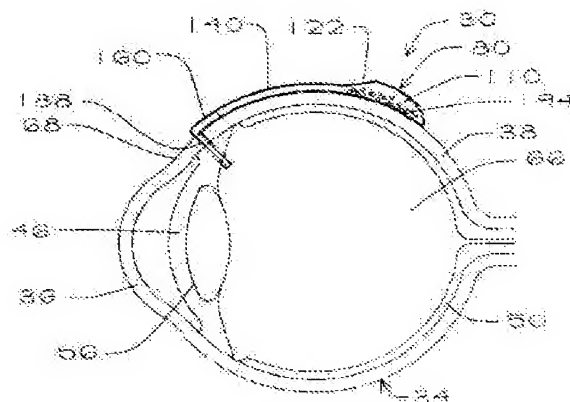


Fig. 2

Thus, Avery does not teach or suggest a securing mechanism near the distal end of the cannula nor would there be any teaching or suggestion to modify Avery to provide such a securing mechanism. Avery's pre-formed rigid tube 140 and elbow provide the end of Avery's device positioned at a desired location within the vitreous. The vitreous is a viscous fluid and, thus, even if there was a securing mechanism provided at the distal end of the device, it would not serve any purpose in securing the distal portion of the device within the viscous vitreous fluid.

In view of the above, it is respectfully submitted that claim 1 is clearly not anticipated by Avery. Reconsideration and withdrawal of the rejection is respectfully requested.

## 2. 35 U.S.C. §103 Rejections

Claims 2-6, 8-22 and 24 are rejected under 35 U.S.C. §103(a) over Avery and U.S. Patent No. 5,454,796 to Krupin (hereinafter “Krupin”) or U.S. Patent No. 5,370,607 to Memmen (hereinafter “Mennen”). Applicants respectfully traverse.

As set forth above, claim 1 is not taught or suggested by Avery.

Krupin is cited for allegedly describing a ring-shaped delivery device. However, this does not remedy the above-noted deficiencies in Avery. Krupin is directed towards a device that treats glaucoma by draining fluid out of the anterior chamber of the eye. As such, Krupin describes a plate 16 that is designed for positioning on the outer surface of the eye in one of four quadrants between two rectus muscles (e.g. 50, 52 as shown in Fig. 5). A tube 14 is configured to extend from the plate across the surface of the eye and terminate in the anterior chamber 42. Krupin does not teach or suggest a securing mechanism near the distal end of the tube 14 nor is there any teaching or suggestion to modify Krupin to provide such a securing mechanism – rather, this teaching comes purely from Applicants’ disclosure.

Like Krupin, Memmen also does not remedy the above-noted deficiencies in Avery. Krupin describes a device and method for treating glaucoma by draining fluid out of the anterior chamber of the eye. As such, Memmen’s device includes a reservoir 20 configured so as to be positioned in the same way as Krupin with a drainage tube 60 configured to extend from the reservoir 20 into the anterior chamber of the eye. Memmen does not teach or suggest a securing mechanism near the distal end of the tube 60 nor is there any teaching or suggestion to modify Memmen to provide such a securing mechanism – rather, this teaching comes purely from Applicants’ disclosure.

Thus, clearly no combination of Avery, Krupin, and Memmen would provide Applicants' subretinal delivery device and methods of treatment as set out in claim 1. Claims 2-6, 8-18, and 25-26 depend from claim 1 and, thus, also are patentable over Avery, Krupin, and Memmen. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants further recite, in amended claim 24, a subretinal delivery device comprising a reservoir and a cannula extending from the reservoir. As set out, the cannula has a length and is configured to extend from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. Further, the cannula has a pointed distal end for insertion through the retina. Still further, the distal end and at least a distal portion of the cannula has a cross-sectional size that allows for disposal and retainment within the subretinal space between the retina and choroid of the eye.

It is submitted that Avery, which describes a sleeve 162 (the portion of the device that extends into the eye and terminates in the vitreous) having a size of 19-20 gauge (approximately 0.81-0.92 mm) is not suitably sized for insertion and retainment in the subretinal space. In addition, Avery is not at all directed towards delivery of a material subretinally, so there is absolutely no teaching or suggestion to modify Avery's device (in view of any teaching of Krupin, Memmen, or otherwise) such that it is suitably sized for insertion and retainment in the subretinal space.

Thus, it is respectfully submitted that claim 24 is patentable over Avery, Krupin, and Memmen. Reconsideration and withdrawal of the rejection is respectfully requested.

### 3. Allowable Claims

Applicants appreciate the notification that claims 19-22 would be allowable if rewritten in independent form. Applicants note that claim 19 already is in independent form, and claims 20-22 as well as new claims 27-29 submitted in Applicants' August 11, 2009 Amendment depend from independent claim 19. Thus, believe that these claims are allowable.

### **CONCLUSION**

In view of the forgoing, Applicants believe the pending application is in condition for allowance. Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

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Respectfully submitted,

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